

REMARKS

Applicant requests reconsideration of the application in view of the foregoing amendments and the discussion that follows. The status of the claims as of this response is as follows: Claims 1-6 and 8-60 are pending, Claim 7 having been previously canceled. Claims 1, 8, 23, 48, 53, 58 and 60 have been amended herein.

The Amendments

Claim 1 was amended to recite that v is 2 to 6. Support therefor is in the specification, for example, page 16, line 16, where v" is a subset of v.

Claims 8, 53, 58 and 60 were amended to recite that v' is 2 to 6. Support therefor is in the specification, for example, page 16, line 16, where v" is a subset of v'.

Claim 23 was amended to recite that v'" is 2 to 6. Support therefor is in the specification, for example, page 16, line 16, where v" is a subset of v'''.

Rejection under 35 U.S.C. 103

Claims 1-6, 8-19, 21, 23-28, 30, 32-35, 40-43, 48-52 and 58-59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wang, *et al.* (U.S. Patent Publication No. 20020090661 A1) (Wang). The reference discloses tracers and their synthesis and use in an immunoassay for the detection of controlled drugs such as amphetamine (APM), methamphetamine (MAPM) and their derivatives, in a biological or aqueous sample. In particular, the disclosure of Wang provides methods for synthesizing tracers, in which a non-controlled substance is both the starting material in tracer synthesis and the binding site on the resulting novel tracer for the antibody, thereby eliminating the necessity of using controlled substances as starting materials. In addition, the tracers of Wang can be used as an analyte analog in an immunoassay, such as a continuous flow displacement immunoassay.

Without acquiescing in the position of the Office action, Applicant submits that Claims 1-6, 8-19, 21, 23-28, 30, 32-35, 40-43, 48-52 and 58-59 are patentable over Wang, who fails to disclose or suggest the compounds having v and its variants v', v" and v''' being 2 to 6. Such compounds are not mere chain homologs of compounds disclosed by Wang.

The Wang reference does not suggest the compounds claimed in Claim 14 and those claims depending therefrom. For example, Wang does not disclose or suggest at least compounds as in Claim 14 wherein v" is 2 to 6 and wherein the linker comprises >SO₂ as claimed in Claim 14 and those claims depending therefrom.

Claims 20, 22, 29, 31, 36-39, 44-47, 53-57 and 60 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wang in view of Heiman, *et al.* (U.S. Patent No. 5,262,333) (Heiman). Heiman's disclosure relates to a method and reagents for determining amphetamine and d-methamphetamine in a biological fluid, such as urine. In particular, the disclosure relates to improvements in a fluorescence polarization immunoassay procedure for determining the presence of amphetamine and d-methamphetamine in a single assay and to a class of tracer compounds employed as reagents in such procedures. The tracer is a phenylethylamine derivative, which is linked to a fluorescein derivative by, for example, an amido, amidino, triazinylamino, carbamido, thiocarbamido, carbamoyl, thiocarbamoyl, or sulfonylcarbamoyl group. The procedure described includes pretreatment of the biological sample to eliminate cross reactants such as beta-hydroxyphenethylamine by preincubating the sample solely with an aqueous periodate solution having a pH from about 4.0 to about 7.5 without adjustment to an alkaline pH, and contacting the sample with riboflavin binding protein to reduce interference from fluorescent components in the sample. The procedure also maintains the cross reactivity of the immunoassay for tyramine at about 0.4% and for 1-methamphetamine below about 5.1% and eliminates the necessity of using controlled substances as starting materials.

Without acquiescing in the position of the Office action, Applicant submits that Wang fails to disclose or suggest the compounds having v and its variants v', v" and v''' being 2 to 6. Such compounds are not mere chain homologs of compounds disclosed by Wang. Heiman does not disclose or suggest the aforementioned compounds of the claims. Accordingly, a combination of the teachings of the references does not yield the method and kit inventions of Claims 20, 22, 29, 31, 36-39, 44-47, 53-57 and 60.

Claims 20, 22, 29, 31, 36-39, 44-47, 53-57 and 60 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wang in view of Hui, *et al.* (U.S. Patent Publication No. 20030175995) (Hui). The Hui reference discloses compounds including

haptens, intermediates, and immunogens that are useful in the production of antibodies specific for the methylenedioxy class of amphetamine derivatives.

Applicant submits that the above claims and claims depending therefrom are patentable over the combination of Wang and Hui. Without acquiescing in the position of the Office action, Applicant submits that Wang fails to disclose or suggest the compounds having v and its variants v', v'' and v''' being 2 to 6. Such compounds are not mere chain homologs of compounds disclosed by Wang and Hui does not disclose or suggest the aforementioned compounds of the claims. Accordingly, a combination of the teachings of the references does not yield the method and kit inventions of Claims 20, 22, 29, 31, 36-39, 44-47, 53-57 and 60.

Conclusion

Applicant has demonstrated that Claims 1-6 and 8-60 satisfy the requirements of 35 U.S.C. 103. Allowance of the above-identified patent application, it is submitted, is in order. In any event the above amendments narrow the number of issues and place the application in better form for consideration on appeal.

The amendments and arguments made above should not be construed as abandonment by Applicant of the subject matter of the claims as originally filed including claims to stereoisomers. Applicant reserves the right to pursue such subject matter in continuation applications.

Respectfully submitted,



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